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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/475,158	12/30/1999	Thomas J. Gardella	0609.4780001	6018
26111	7590	10/02/2003	EXAMINER	
STERNE, KESSLER, GOLDSTEIN & FOX PLLC			LI, RUIXIANG	
1100 NEW YORK AVENUE, N.W.			ART UNIT	
WASHINGTON, DC 20005			PAPER NUMBER	
			1646	

DATE MAILED: 10/02/2003

*JD*

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/475,158

Applicant(s)

GARDELLA ET AL.

Examiner

Ruixiang Li

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-11 and 14-40 is/are pending in the application.
- 4a) Of the above claim(s) 15-36 and 38-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11, 14, and 37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## **DETAILED ACTION**

### **I. Status of Application, Amendments, and/or Claims**

The amendment filed in Paper No. 20 on May 2, 2003 has been entered in full. Claims 12 and 13 have been canceled. Claims 1, 5-8, 11, and 14 have been amended. Claims 1-11 and 14-40 are pending. Claims 1-11, 14, and 37 are under consideration.

The Examiner who works on your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Ruixiang Li of Art Unit 1646.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

### **II. Withdrawn Objections and/or Rejections**

The objection to claims 7 and 8 in Paper No. 18 (November 6, 2002) has been withdrawn in view of Applicants' amendment to the claims.

The rejection of claims 5-7, 11, 12, and 14 under 35 U. S. C. § 112, 2<sup>nd</sup> paragraph as set forth in Paper No. 18 (November 6, 2002) has been withdrawn in view of Applicants' amendment to claims 5-7, 11, and 14 and cancellation of claim 12.

Applicants' cancellation of claims 12 and 13 has made the rejection of the claim under 35 U. S. C. § 112, 1<sup>st</sup> paragraph (scope enablement) as set forth in Paper No. 18 (November 6, 2002) moot.

### **III. Objection to Specification**

The objection to specification as set forth in Paper No. 18 (November 6, 2002) remains. The specification is objected to because SEQ ID NO: 3 and SEQ ID NO: 9 are identical; SEQ ID NO: 6 and SEQ ID NO: 11 are identical; whereas SEQ ID NO: 5 and SEQ ID NO: 13 are identical. Each sequence should be identified by a unique SEQ ID NO. Correction is required.

### **IV. Claim Rejections Under 35 U. S. C. § 112, 1<sup>st</sup> Paragraph (Scope Enablement)**

The rejection of claims 1-11, 14, and 37 under 35 U. S. C. § 112, 1<sup>st</sup> paragraph (Scope Enablement), as set forth in Paper No. 18, remains.

At the second paragraph of page 11 and the third paragraph of page 13, Applicants argue that Applicants have amended claim 1 and cancelled claim 13 in order to address the Examiner's concerns that claims 1-12, 14, and 37 are directed to a compound or polypeptide with no limitation regarding its biological activity and the specification does not reasonably provide enablement for a compound that does not have biological activity.

This has been fully considered but is not deemed to be persuasive for the following reasons. While the cancellation of claims 12 and 13 has made the rejection of claims 12 and 13 under 35 U. S. C. § 112, 1<sup>st</sup> paragraph (Scope Enablement) moot, the rejection of other claims under 35 U. S. C. § 112, 1<sup>st</sup> paragraph (Scope Enablement) remains. It is noted that claim 1 has been amended by reciting in part carboxy terminal binding domain of PTH (1-34) or PTHrP(1-34); however, such an amendment fails to

overcome the rejection set forth in paper No.18 because there is no specific functional limitation for the claimed compounds. Merely reciting "wherein said compound is biologically active" does not limit the scope of claimed invention because the biological activity is not defined. Due to the lack of an effective functional limitation, the "functional derivatives" recited in claims 7-9 are also clearly not enabled.

Beginning at the third paragraph of page 11, Applicants argue that Applicants have provided ample guidance as to the type of linkers that are suitable for use with the present invention and have demonstrated the practical feasibility of several of these linkers. Applicants further submit that the linkers mentioned in the specification are examples of linkers that were well known to the skilled artisan in protein biochemistry and were commercially available or could have been easily synthesized at the time of the invention.

This has been fully considered but is not deemed to be persuasive because claim 1 recite in part "L is a linker molecule present n times", whereas the specification discloses "L is a linker sequence of any useful length" (lines 3-4 of page 32). Thus, the claims encompass a genus of linkers without defined composition and structure. The specification fails to provide sufficient guidance and working examples on how to make and/or use such a broad of genus of linkers and consequently fails to enable an artisan to make and/or use a compound comprising an undefined linker. It is further noted that while linkers are known in the art, the specification simply fails to demonstrate whether any linkers known in the art actually work in the instant case.

At the top of page 13, Applicants argue that the binding specificities of PTH and

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PTHrP were well known in the art at the time of the invention. Applicants further submit that Applicants have amended claim 1 to more clearly point out and claim the subject matter of the invention.

This has been fully considered but is not deemed to be persuasive because claim 1 merely recites, in part, "B is a carboxy terminal binding domain of PTH(1-34) or PTHrP(1-34), which is not equivalent to the parathyroid hormone's receptor binding domain. Since the compound that the binding domain binds is not defined, the claims does not define the binding specificities of B.

## **V. Conclusion**

No claims are allowed.

**THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (703) 306-0282. The examiner can normally be reached on Monday-Friday, 8:30 am-5:00 pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Ruixiang Li  
Examiner  
September 29, 2003

  
YVONNE EYLER, PH.D  
SUPERVISORY PATENT EXAMINER  
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